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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,313	08/24/2001	Henry Yue	PF-0706 USN	4434
22428	7590	09/22/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			BUGAISKY, GABRIELE E	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,313

Applicant(s)

YUE ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/7/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17,19,22,25-30,32-34,36-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,9,10,13-17,19,22,25-30 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7,11,12,36-38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of 7/7/2004 is acknowledged. The status of the claims is as follows: claims 8, 18, 20-21, 23-24, 31, 35 have been cancelled, rendering any rejections of these claims as moot and claims 1-7, 9-17, 19, 22, 25-30 32-34, 36-38 and 40 are currently pending. Claims 1-2, 9-10, 13-17, 19, 22, 25-30 and 32-34 have been withdrawn; claims currently under consideration are 3-7, 11-12, 36-38 and 40.

Oath/Declaration

The new declarations are acknowledged.

Specification

The objection to the disclosure because of an embedded hyperlink is withdrawn, based upon the amendment.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of trademarks (e.g., SEPHAROSE, PICOGREEN, SEPHADEX) has been noted in this application (pages 66, line 22, page 59 lines 24-25 and page 60, line 6, respectively.. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

The objection to claims 11-12 and 38 is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6-7, 11-12, 36, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To determine whether there is correspondence between the generic invention of the claims and the written description is necessary to determine whether the description conveys to one skilled in the relevant art that applicant was in possession of the claimed genus at the time the application was filed. To this end, it is appropriate to inquire whether a number of species representative of the genus are described in complete structural terms or, alternatively, with reference to other identifying characteristics, *e.g.*, partial structure, chemical properties, functional properties, *etc.* What constitutes a “representative number” of species for any given genus depends in part on whether the level of skill in the art, the teachings in the disclosure, or

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teachings in the prior art establish predictability as to the structural properties characteristic of the genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of the nucleotides encoding the protein of SEQ ID NO:1, , the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The molecule itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the only nucleic acids encoding the protein of SEQ ID NO:1, and the recited fragments of those nucleic acids comprising that sequence, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is

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reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 3, 6-7, 11-12, 36 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding a protein comprising SEQ ID NO:1, and the recited fragments of those nucleic acids does not reasonably provide enablement for any nucleotide with a certain degree of sequence similarity to SEQ ID NO:3 (or encoding a protein of SEQ ID NO:1) which encoded protein has localization and transport activity.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988), the issue of enablement in molecular biology was considered. There are eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. Although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable. Here, one has description of two members of a family of human sorting nexins, , but the claims encompass any nucleic acid encoding a sorting protein that shares a specific degree of sequence similarity to a nucleic acid sequence of SEQ ID NO:1. the specification does not teach how to differentiate between different members of the nexin gene family; thus it is not clear that a nucleic acid encoding a sorting nexin protein with 70%

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sequence identity to SEQ IDNO:1 is *a priori* a variant of the disclosed gene or a different member of the family. One is thus given an invitation to experiment try to isolate putative homologs and determine identity of biological function. In light of the minimal guidance, the presence of but a single working example of nucleic and encoding SEQ ID NO:1 and the breadth of the claims, the Examiner concludes that one has been presented with an invitation to experiment in order to try to obtain the claimed nucleic acids.. Such a task is deemed to constitute undue experimentation.

The rejection of claims 3 and 6-7 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn based upon the amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 11 and 36 under 35 U.S.C. 102(a) as being anticipated by TANAKA *et al.* is withdrawn, based upon the amendment.

The rejection of claims 3, 11-12, 36-38 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by MYERS is withdrawn, based upon the amendment.

The rejection of claims 3, 7, 11-12 and 36 under 35 U.S.C. 102(e) as being anticipated by Byatt *et al.* (US 20020137160) is withdrawn, based upon the amendment.

Double Patenting

Claims 3-7, 11-12 36-38, and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12, 18 and

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20 of copending Application No. 09/488725. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant SEQ ID NO:3 is identical to SEQ ID NO:8393 of the copending application; instant SEQ ID NO:3 is one species of 10,289 recited sequences of the copending claims. This application has an inventor in common with 09/488725 (Y. Tom TANG) whose residence is identical to that of Yuanhua T. Tang of the copending application. It is deemed highly unlikely that two different YT TANGs reside at the same address in San Jose , CA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Conclusion

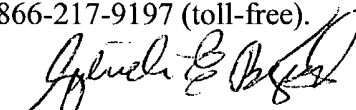
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

19 September 2004